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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,176	12/13/2000	Josef V. Koblish	15916-279	8413

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Henricks Slavin & Holmes LLP
Suite 200
840 Apollo Street
El Segundo, CA 90245

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/04/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/737,176

Applicant(s)

KOBISH ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-16,18-28,33,36,37,39 and 41-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6-16,18-28,33,36,37 and 49 is/are allowed.
- 6) ☒ Claim(s) 39,41-48 and 50-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25. 6) ☐ Other: _____

Art Unit: 3739

Applicant's amendments and comments, received October 14, 2003, have been fully considered by the examiner. The following is a complete response to the October 14, 2003 communication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 41-43 and 54-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab ('392).

Saab discloses a surgical probe which includes a relatively short shaft (66) having distal and proximal portions, and an inflatable, energy transmitting therapeutic element (72) at the distal end. An infusion lumen (64) and a ventilation lumen (68) extend proximally from the inflatable member and there is a source of cooling fluid connected to the probe and adapted to maintain pressure and continuously infuse and vent the cooling fluid (col. 7, lines 5-20). Various heating options are available, as well as simultaneous heating while cooling (col. 11, lines 12-45). There is no perfusion of the fluid through the balloon surface.

Claims 50 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Stern et al ('470).

Art Unit: 3739

Stern et al discloses a probe which includes a relatively short, relatively stiff shaft for treating the uterine cavity. The probe has a distal portion including a means for inflating and transmitting current to tissue at a level sufficient to cause lesions. The inflating means is a balloon (14) which includes RF energy delivery means to deliver ablative energy to tissue. The balloon does not allow perfusion of fluid through the balloon surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab ('392) in view of the teaching of Deslauriers et al ('678).

Saab fails to specifically disclose the probe as having a malleable property to allow for the shaping of the device prior to insertion to more effectively conform to a tissue treatment area.

Deslauriers et al disclose a balloon device which includes a probe shaft with an inflatable balloon at the distal portion similar to the Saab device. In particular, Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

Art Unit: 3739

To have provided the Saab probe with a malleable shaft to facilitate its insertion into a body cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 46-48 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab ('392) in view of the teaching of Abele ('311).

As addressed previously, Saab provides a means to continuously infuse and ventilate a cooling fluid into a balloon to maintain a desired pressure (col. 7, lines 5-20). However, Saab fails to specifically disclose the use of a pressure sensor to determine the pressure in the balloon and control the delivery of fluid to maintain a desired pressure.

Abele et al disclose an analogous device which includes a probe having an inflatable member at the distal end and means for effecting thermal transfer to tissue via the inflatable member. More specifically, Abele et al teach that it is known to provide pressure sensors in the inflatable member to monitor the pressure of the balloon and control the infusion/exhaust of a fluid to maintain a desired pressure at the balloon.

To have provided the Saab device with pressure sensors for monitoring and maintaining the balloon at a desired inflation pressure would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Abele et al.

Art Unit: 3739

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) in view of the teaching of Deslauriers et al ('678).

Stern et al disclose a short, rigid probe for the treatment of uterine tissue. As addressed previously, Stern et al provide an inflatable member at the end of the probe for delivering RF current to tissue to create lesions/ablate the uterine tissue. Stern et al fail to specifically teach that the probe is malleable.

Deslauriers et al disclose a balloon probe device which includes a probe shaft with an inflatable balloon at the distal portion just as in Stern et al. In particular, Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

To have provided the Stern et al probe with a malleable shaft to facilitate its insertion into the uterine cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 39, 41-43 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) in view of the teaching of Saab ('392).

Stern et al discloses a probe device which includes an inflatable member disposed at the distal end of the probe. As addressed previously, the inflatable member includes RF energy means for providing ablative RF current to tissue. While Stern et al teach that the balloon member is inflated during treatment, there is no specific teaching

Art Unit: 3739

that a fluid is continuously infused and ventilated to maintain a desired pressure in the balloon. Rather, Stern et al simply inflate the balloon to the desired pressure and maintain the fluid within the balloon until the procedure is complete.

Saab discloses another system which includes a probe body with an inflatable member disposed at the distal end of the probe. Saab teach the use of the inflatable member to transfer heat to tissue, and further specifically teach that a fluid may be continuously infused and ventilated to maintain the balloon at a desired pressure (col. 7). Also, Saab teaches that it is advantageous to provide a circulating cooling fluid to inflate the balloon while an alternative energy source is used to heat the tissue (col. 11).

To have provided the Stern et al balloon with means to provide continuous infusion and ventilation of a cooling fluid to enhance the heating effect of the RF treatment means would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Saab.

Claims 44 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Deslauriers et al ('678).

The combination of the Saab teaching with the Stern et al device has been addressed previously. Neither of these references specifically teaches of a malleable probe body to facilitate insertion of the device into a body cavity.

Deslauriers et al disclose a balloon device which includes a probe shaft with an inflatable balloon at the distal portion similar to the Saab device. In particular,

Art Unit: 3739

Deslauriers et al teach that it is advantageous to provide the shaft as a malleable member to facilitate its insertion into the body passage and to conform to the desired tissue site.

To have provided the Stern et al probe, as modified by the teaching of Saab, with a malleable shaft to facilitate its insertion into a body cavity and to conform to the shape of the desired treatment area would have been an obvious modification for one of ordinary skill in the art, particularly in view of the teaching of Deslauriers et al.

Claims 46-48 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Abele ('311).

The combination of the Saab teaching with the Stern et al device as been addressed previously. While Saab provides a means to continuously infuse and ventilate a cooling fluid into a balloon to maintain a desired pressure (col. 7, lines 5-20), there is no disclosure of using a pressure sensor to determine the pressure in the balloon and control the delivery of fluid to maintain a desired pressure.

Abele et al disclose an analogous device which includes a probe having an inflatable member at the distal end and means for effecting thermal transfer to tissue via the inflatable member. More specifically, Abele et al teach that it is known to provide pressure sensors in the inflatable member to monitor the pressure of the balloon and control the infusion/exhaust of a fluid to maintain a desired pressure at the balloon.

Art Unit: 3739

To have provided the Stern et al device, as modified by the teaching of Saab, with pressure sensors for monitoring and maintaining the balloon at a desired inflation pressure would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Abele et al.

Claims 45 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al ('470) and Saab ('392) and further in view of the teaching of Qian ('028).

As addressed previously, Stern et al disclose a balloon apparatus which includes means for providing RF current to tissue in order to ablate the treatment tissue. Saab further discloses the known use of circulating a cooling fluid to enhance the effects of a heat treatment catheter. Neither reference discloses a porous balloon which allows for the perfusion of a conductive fluid to tissue to enhance RF treatment of tissue.

The Qian device is substantially analogous to the Stern et al device in that it is a probe with an inflatable member which includes means to deliver RF current for the treatment of tissue. In particular, Qian teaches that it is known to provide the balloon with micropores which allows a certain amount of conductive fluid to be perfused to the tissue site to enhance the effect of the RF energy being delivered to tissue.

To have provided the Stern et al device, as modified by the teaching of Saab, with a porous balloon to allow a portion of the conductive fluid to perfuse tissue and enhance the delivery of RF energy to tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Qian.

Art Unit: 3739

Allowable Subject Matter

Claims 1, 3, 4, 6-16, 18-28, 33, 36, 37 and 49 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments with respect to claims 39 and 41-62 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

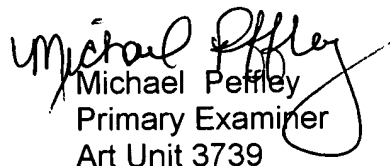
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

Art Unit: 3739

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Michael Peffley
Primary Examiner
Art Unit 3739

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December 1, 2003